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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/072,414 | 02/05/2002 | Calvin F. Quate | 3053.1C | 5371 |

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[REDACTED] EXAMINER

KIM, YOUNG J

| ART UNIT | PAPER NUMBER |
|----------|--------------|
| | 1637 |

DATE MAILED: 09/20/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | |
|------------------------------|------------------------|---------------------|
| Office Action Summary | Application No. | Applicant(s) |
| | 10/072,414 | QUATE ET AL. |
| | Examiner | Art Unit |
| | Young J. Kim | 1637 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on _____.
 2a) This action is **FINAL**. 2b) This action is non-final.
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1 and 14-31 is/are pending in the application.
 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
 5) Claim(s) _____ is/are allowed.
 6) Claim(s) 1 and 14-31 is/are rejected.
 7) Claim(s) 14, 15, 18 and 21 is/are objected to.
 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
 10) The drawing(s) filed on 05 February 2002 is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ . |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date <u>11/26/2002</u> . | 6) <input type="checkbox"/> Other: _____ . |

DETAILED ACTION

Preliminary Remark

Petition under 37 CFR §§ 1.181, 1.182, 1.183

Applicants' petition to allow submission references as electronic copies on CD-ROM and officially make them of record, received on November 26, 2002, has been DISMISSED.

Applicants' attention is directed to 37 CFR § 1.52(e) which allows submissions of portions of patent applications on CD-ROM and CD-R media, *when the data is submitted as an ASCII file format*. Other medias such as CD-RW and no other file formats are permitted.

Terminal Disclaimer

The terminal disclaimer filed on February 5, 2002 has been accepted.

Claim status

Claims 2-13 have been canceled without prejudice or disclaimer. Claims 14-31 have been added.

Claims 1 and 14-31 are pending and are under prosecution therefore.

Information Disclosure Statement

The IDS received on November 26, 2002 is acknowledged. A signed copy of its PTO-1449 is attached hereto.

Applicants are advised that references O through U have not been received and therefore, have been lined-through.

Drawings

The formal drawings filed on February 5, 2002 are acceptable.

Priority/Oath and Declaration

The later-filed application must be an application for a patent for an invention which is also disclosed in the prior application (the parent or original nonprovisional application or provisional application); the disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994).

However, newly submitted claims 14-31 contain new matter, which previously had not been claimed nor supported by the instant specification.

Specifically, new claims 14-31 is drawn to a broadened method and a sensor which does not require cantilever, but rather a substrate comprising biopolymers thereon. Such limitation had not been previously claimed, nor had it been restricted in the previous prosecution history.

The instant specification also fails to provide proper written support for this broaden claims:

“The present invention provides a method for determining whether a chemical interaction has occurred between naturally occurring bio-polymers which are non-identical binding partners through detecting a physical or chemical change on a ***micromechanical device called a cantilever.***” (page 2, beginning at the bottom paragraph to page 3, 1st paragraph).

The specification further describes this cantilever as, by way of analogy, “a diving board which has been reduced to a very small size,” (page 3, 1st paragraph, line 3).

“According to the method of the present invention, a chemical interaction between naturally occurring bio-polymers which are non-identical binding partners is monitored by

detecting a physical or chemical change through deflection of a cantilever.” (page 7, 2nd paragraph).

Therefore, the instant specification does not provide a proper support for the broadened claims which embrace a method/sensor involving solid substrate comprising bio-polymers (*i.e.*, microarray, biochip, microfluidic device) which do not employ cantilevers.

Therefore, claims 14-31 are considered to be new matter and thus would not benefit the prior filing dates of its parent applications under 35 U.S.C. 120. Additionally, Applicants must supply a new oath and declaration identifying the instant application as a Continuation-in-part.

Claim Objections

Claims 14, 15, 18, and 21 are objected to because of the following informalities: claims interchangeably recite the term, “bio-polymers” and the term, “biopolymers.” For the sake of consistency, Applicants are advised to use consistent claim language.

Appropriate correction is suggested.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 22, 26, and 27 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is indefinite because while the preamble of the claim recites that the method is for detecting chemical interaction between naturally occurring “bio-polymers,” none of the recited steps involve the use of said bio-polymers.

Claim 22 is indefinite for reciting the phrase, “the biopolymer *material*” because there is no proper antecedent basis for a “biopolymer material.”

Claim 26 is indefinite for reciting the phrase, “the method...wherein there is a plurality of polynucleotides to form an array,” because it is unclear whether the phrase actively further limits the claims to use an array of polynucleotides or it simply requires that there are a plurality of polynucleotides. If the former interpretation is desired, the phrase could be amended as “the method...wherein there is a plurality of polynucleotides, thereby forming an array.”

Claim 27 is indefinite for reciting the phrase, “sensor is arranged to produce an array,” because it is ambiguous as to whether the sensor *is* an array, or the sensor is arranged in a manner to produce an array, but is not an array itself.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The present rejection is based on the denial of the priority under 35 U.S.C. 120 to the parent application, rendering the instant claims having the filing date of February 5, 2002.

Claims 14-31 are rejected under 35 U.S.C. 102(b) as being anticipated by Corn et al. (U.S. Patent No. 6,127,129, issued October 3, 2000).

Corn et al. disclose a sensor apparatus for detecting nucleic acid hybridization (thus interaction between naturally occurring biopolymers), said sensor apparatus comprising: a) a gold support (column 4, line 49); b) a self assembled surface on the gold comprising alkanethiol molecules (column 4, lines 55-61); c) nucleic acid connected to the self assembled surface (column 4, line 60); and d) a detector for determining hybridization (column 4, lines 29-38).

The sensor is disclosed as being arranged in an array format (column 12, lines 46-48; Figure 1).

Corn et al. disclose that the disclosed sensor is used in molecular assay, such as hybridization assay, which would necessarily require the steps of introducing at least one biopolymer analyte molecule to said surface, followed by detecting the change based on binding between the biopolymer and the biopolymer analyte (Figure 5; column 3, line 21-23; column 5, lines 25-39; column 13, lines 1-35).

Therefore, Corn et al. anticipate the invention as claimed.

Claims 14-31 are rejected under 35 U.S.C. 102(b) as being anticipated by Kayyem (Clinical Chemistry, July 1999, vol. 45, no. 6, supplement S12, IDS ref# Z) in light of Yu et al. (Abstracts of Papers of the American Chemical Society, March 1999, vol. 217, no.1, IDS ref# V).

Kayyem discloses a method of detecting DNA hybridizations on a microchip, wherein said microchip comprises capture probes immobilized to gold microelectrodes through

Art Unit: 1637

“molecular wires.” Signals which depends on probe/target interaction are then disclosed as being generated through the molecular wire, resulting in the interpretation of their interaction (page S12).

While Kayyem does not explicitly describe the chemical makeup of the “molecular wires,” Yu et al. explicitly disclose that said “molecular wires” comprise self-assembled surface comprising alkanethiol molecules (section 078, Yu et al.).

Therefore, Kayyem anticipates the claimed sensor and the method of using the sensor to detect biopolymer to biopolymer interactions.

Double Patenting

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a ***terminal disclaimer*** **cannot overcome** a double patenting rejection based upon 35 U.S.C. 101.

Claim 1 is rejected under 35 U.S.C. 101 as claiming the same invention as that of claim 1 of prior U.S. Patent No. 6,203,983 B1 (issued March 20, 2001). This is a double patenting rejection.

Claim 1 of the instant application and claim 1 of U.S. Patent No. 6,203,983 are identical in scope.

Claim 1 of the instant application recites that a surface of the cantilever is prepared with, “a binding partner” and, “analyte molecules” are introduced as opposed to the cantilever being prepared with, “bio-polymer binding partner,” and the, “bio-polymer analytes” being introduced in the ‘983 patent. However, the preamble of instant claim 1 is drawn to a method of detecting interaction between naturally occurring *bio-polymers* and thus one skilled or of ordinary skill in the art would readily recognize that said, “binding partner,” and said, “analyte molecules” are indeed bio-polymers, resulting in no difference between claim 1 of the ‘983 patent and claim 1 of the instant application.

Cancellation is required.

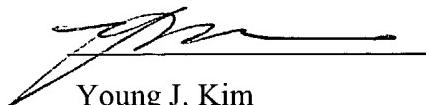
Conclusion

No claims are allowed.

Inquiries

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Young J. Kim whose telephone number is (571) 272-0785. The Examiner can normally be reached from 8:30 a.m. to 6:00 p.m. Monday through Thursday. If attempts to reach the Examiner by telephone are unsuccessful, the Primary Examiner in charge of the prosecution, Dr. Kenneth Horlick, can be reached at (571) 272-0784. If the attempts to reach the above Examiners are unsuccessful, the Examiner's supervisor, Gary Benzion, can be reached at (571) 272-0782. Papers related to this application may be submitted to Art Unit 1637 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 CFR 1.6(d)). NOTE: If applicant does submit a paper by FAX, the original copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED, so as to avoid the processing of duplicate papers in the Office. All official

documents must be sent to the Official Tech Center Fax number: (703) 872-9306. For Unofficial documents, faxes can be sent directly to the Examiner at (571) 273-0785. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (571) 272-1600.



Young J. Kim
Patent Examiner
Art Unit 1637
9/16/04

YOUNG J. KIM
PATENT EXAMINER

yjk